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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

60 8th Street, N.E.
Atlanta, Georgia 30309

October 5, 2000

VIA FEDERAL EXPRESS

Khanh Le Duong, Owner
T & P
4441 Briarcliff Road
Atlanta, GA 30345

Warning Letter
01-ATL-3

Dear Mr. Duong:

On June 20, 2000, the Food and Drug Administration (FDA) conducted an inspection of your sprout growing facility located at Atlanta, Georgia. During that inspection, our investigators documented practices at your facility that concern us and cause your mung bean sprouts to be in violation of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act through links in FDA's home page at *www.fda.gov*.

Specifically, our inspection revealed that your firm's sprouts are adulterated within the meaning of section 402(a)(4) of the Act because they are being produced under insanitary conditions that may render the sprouts injurious to health. The conditions under which the sprouts are being produced are considered insanitary since effective preventive controls, particularly microbial testing of spent irrigation water, have not been adopted and implemented by your firm, and an effective alternative is not in place.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating. For your information, I have enclosed copies of two guidance documents intended to assist the sprout industry in producing safe products. The two guides are: "Guidance for Industry: Reducing Microbial Food Safety Hazards for Sprouted Seeds" and "Guidance for Industry: Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production." To address our concerns, you could follow the guidance provided in these documents or establish an alternative approach that satisfies the requirements of the Act and regulations.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Please send your reply to Carlos A. Bonnin, Compliance Officer, U.S. Food and Drug Administration, 60 Eighth Street, N.E., Atlanta, Georgia 30309. If you have questions regarding any issue in this letter, please contact Mr. Bonnin at 404-253-1277.

Sincerely,

Ballard H. Graham, Director
Atlanta District

Enclosures

cc: Trung Duong, Assistant Manager
T & P
4441 Briarcliff Road
Atlanta, GA 30345